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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,828	10/29/2003	Steven D. Rosen	UCAL-138DIV	9294
24353	7590 08/02/200	5	· EXAMINER	
	C, FIELD & FRANCERSITY AVENUE	MONSHIPOURI, MARYAM		
SUITE 200				PAPER NUMBER
EAST PALC				

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summany	10/697,828	ROSEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Maryam Monshipouri	1653				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on	1) Responsive to communication(s) filed on					
2a) ☐ This action is FINAL . 2b) ☑ This	This action is FINAL . 2b)⊠ This action is non-final.					
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-29</u> is/are pending in the application.						
4a) Of the above claim(s) <u>5-29</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-4</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Brawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <i>filed 6/04 & 10/03</i> .	Paper No(s)/Mail Dat 5) ☐ Notice of Informal Pa 6) ☒ Other: <u>see attachmen</u>	te atent Application (PTO-152)				

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Art Unit: 1653

Applicant's response to restriction requirement filed 6/1/2005 is acknowledged. Applicant elected Group I invention, claims 1-4 and GST4 α species with traverse. In traversal of restriction requirement applicant argues that it would not be unduly burdensome to perform a search on all the claims together and for that reason the restriction requirement should be withdrawn.

This argument was fully considered but was found **unpersuasive**. This is because as explained in the previous office action, apart from Groups I-II all the inventions of Groups III-VII belong to separate class/subclasses. Hence rejoinder of said inventions clearly does impose an undue burden of searching on the examiner. Applicant is specially reminded that the invention of Group VII needs to be examined in an art unit independent of art unit 1653, wherein current elected invention is being examined.

With respect to inventions of Groups I-II, it should be reminded that even though there may be some overlap between the subject matter of each invention, the searches required for Groups I-II are **not coextensive**. This is because Group II requires a search in class 530/350, which is not relevant to Group I invention. Similarly, the invention of Group I requires a search in class 435/320.1 which is irrelevant to the invention of Group II. Therefore, as applicant can appreciate the rejoinder of Groups I-II also imposes an undue burden of searching on the examiner.

In conclusion, for the reasons set forth above, in addition to reasons provided in the previous office action restriction is maintained and is hereby made **final**.

DETAILED ACTION

Claims 1-4 (and $GST\alpha$ species) are under examination on the merits.

Claims 5-29 are withdrawn as drawn to non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially identical" in claim 3 is unclear.

Applicant has not defined said term in the specification. It is unclear as how much homology to SEQ ID NO:7 or 8 constitutes "substantial". Appropriate clarification is required.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the fragment of glycosyl sulfotransferse of claim 1, namely $GST\alpha$ has to retain transferase activity or not. For examination purposes it is assumed that fragments claimed retain their glycosyl sulfotransferase activity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 2 and 4 are directed to a genera of glycosyl transferases or fragments thereof that have been merely defined by function.

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The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula (or) chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula fro others and can identify many of the species that the claims encompass, accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, in claims 1 and 4, applicant is claiming a genus of proteins merely but they do rather but what they are and such genus does not allow visualization of other members of the genus.

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In claim 2, some structural information bout the GST4 α is provided but said information is inadequate because human glycosyl sulfotransferase is a large family comprising many members such as GST α , GST4 β , GST-3, GST-6 etc. The specification fails to teach how much structural homology exists among all members of human glycosyl sulfotransferase family and specifically how the function of one human species differs from the other and as such the genus of human glycosyl transferases are inadequately described.

With respect o claim 3 as explained above, the term "substantially identical" is unclear. Therefore the structural limitations of the genus of SEQ ID NO:7 and 8 homologs are unclear, rendering the claim subject to written description rejection.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bistrup et al. (U.S. Patent No. 6,365,365, issued 4/2002). Bistrup teaches a human glycosyl

transferase namely GST-3 and fragments thereof prior to this invention. Since glycosyl sulfotransferase of Claim 1 is merely defined by function and the exact functional difference between human GST- α and human GST-3 of Bistrup is not clear it is believed that transferase of Bistrup and fragments thereof meet the limitations of claims 1-2 and 4 of this invention. With respect to claim 3 , since the term "substantially identical" is not clear (see the rejection above) it is believed that GST-3 of Bistrup , which has 49.1% identity to SEQ ID NO:8 of this invention (see the attached alignment) can be considered to be "substantially identical" to SEQ ID NO:8 of this invention anticipating claim 3.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (U.S. Patent No. 6,558,935, issued 5/2003). Tang teaches a human Musculus glycosyl transferase , SEQ ID NO:11 and fragments thereof prior to this invention. Since glycols sulfotransferase of Claim 1 is merely defined by function and the exact functional difference between human GST-α and SEQ ID NO:11 of Tang is not clear it is believed that the transferase of Tang and fragments thereof meet the limitations of claims 1-2 and 4 of this invention. With respect to claim 3, since the term "substantially identical" is not clear (see the rejection above) it is believed that SEQ ID NO:11 of Tang that has 48.0 % identity to SEQ ID NO:7 of this invention (see the attached alignment) can be considered to be "substantially identical" to SEQ ID NO:7 of this invention, anticipating claim 3.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 or (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner

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US-09-190-911-1
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GENERAL INFORMATION:
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              NUMBER OF SEQ ID NOS: 8
SOFTWARE: FastSEQ for Windows Version 3.0
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 CURRENT APPLICATION NUMBER: US/09/190,911
CURRENT FILING DATE: 1998-11-12
EARLIER APPLICATION NUMBER: 09/045,284
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APPLICANT: Rosen, S
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ORGANISM: H. sapiens
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181 FFNLQSLYPILKDPSLNLHIVHLVRDPRAVFRSRERTKGDLMIDSRIVMGQHEQKLKKED 240
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us-10-697-828-8.rai
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US-09-786-240-11
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SEQ ID NO 11
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ORGANISM: Homo sapier
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                                                                                                                                        181 FF
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                                                                                                                                                     179 FFNLOVILYPILISDPALNILRIVHIVRDPRAVILISREAAGDILAADNIĞIVÜĞTNİ GKWVBAD 237
                                                                                          238 PHIRLIREVCRSHVRIAEAATLKP-PPPLRGRYRLVREEDLAKSEPLAKIRALYAFTGLTL 296
                                                                                                                                                                                                     121 SSLEDWENSRALCSAPACDIIPODESSPGLTAGSCAVNSPLKLLEKACRSYSHVVLKEVR 180
                                                                                                                                                                                                                               119 SAFFYWATSRALCSPPACSAFPRGTISKODVCKTLCTROPESLARE
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                                                                                                                                                                                                                                                                            61 LFGQHPDVFYLMEPAWHVWMTFKQSTAWMLHMAVRDLIRA
                                                                                                                                                                                                                                                                                                          60 LFSQHPDVFYLMEPAWHVWTTLSQGSAATLHMAVRI
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         357 LGYRHVRSEQ
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                       TPQLEAWIHNITHGSGIGKPIEAFHTSSRNARNVSQAWRHALPFTKILRVQEVCAGALQL 356
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LIPHLQTWVHNITRGKGMGD--HAFHTNARDALNVSQAWRWSLPYBKVSRLQKACGDAMNL 356
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                                                                 YYVMQVICQSQLEIYK--TIQSLPKALQERYLLVRYEDLARAPVAQTSRMYEFVGLEF 298
                                                                                                            MLQSLYPILKOPSLNLHIVHLVRDPRAVPRSRERTIKCDLMSDSRLYMGGHEQKLKKED 240
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TITLE OF INVENTION: GLYCOSYL SULFOTRANSFERASE-3
FILE REFERENCE: 6510-107CIP
CURRENT APPLICATION NUMBER: US/09/190,911
CURRENT FILING DATE: 1998-11-12
EARLIER APPLICATION NUMBER: 09/045,284
EARLIER FILING DATE: 1998-03-20
NUMBER OF SEQ ID NOS: 8
SOFTWARE: FastSEQ for Windows Version 3.0
SOFTWARE: FastSEQ for Windows Version 3.0
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TYPE: PRT
ORGANISM: H.
S-09-190-911-1
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Patent No. 6365365
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APPLICANT: Hemmerich, Stefan
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   APPLICANT: Rosen, Steven D.
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        1, MRIPRESSTVMLSLIMVQTGILVE---LVSRQVPS-SPAGLGERVHVLVLSSWRSGSSEV
                                                                                                                                                                                                                                                                                                                                                       Similarity
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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           LTPQLQTWIHNITHGSGPGARREAFKTTSRDALSVSQAWRHTLPFAKIRRVQELCGGALQ 354
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        EDOPYYVMQVICQSQLEİYK-TIQSLİKALQERYLLİVRYEDLARAPVAQTSRMYEFVGLE 297
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               GQLFGQHPDVFYLMEPAWHVWMTFKQSTAWMLHMAVRDLIRAVFLCDMSVFDAYMEPGPR 118
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        PLPHLQTWVHNITRGKGMG--DHAFHTNARDALNVSQAWRWSLPYEKVSRLQKACGDAMN 355
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                                                                                                                                                                GQLFGQHPDVFYLMEPAWHVWMTFKQSTAWMLHMAVRDLTRAVFLCDMSVFDAYMEPGPR
                                                                                                                                                                                                    GQLFSQHPDVFYLMEPAWHVWDTLSQGSAPALHMAVRDLIRSVFLCDMDVFDAYL-PWRR 115
                                                                                                                                                                                                                                                MLLPK--KMKLLLFLVSQMAILALFFHMYSHNISSLSMKAQPERMHVLVLSSWRSGSSFV
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                                      VRFFNLQVLYPLLSDPALNLRIVHLVRDPRAVLRSREQTAKALARDNGIVLGTNGTWV-E
    VRFFNLÓSLYPLLKDÞSLNLHIVHLVRDPRAVFRSRERTKGDLMIDSRIVMGQHEQKLKK 238
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05-09-786-240-11
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SOFTWARE: PERL Program
SEQ ID NO 11
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Matches 215; Conserv
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PRIOR APPLICATION NUMBER: 09/150,657; unassigned; 09/186,779; unassigned; 60/133,642
PRIOR FILING DATE: 1998-09-10; 1998-09-10; 1998-11-04; 1998-11-04; 1999-05-11
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             APPLICANT: HILLMAN, Jennifer L.
APPLICANT: AZIMZAI, Yalda
TITLE OF INVENTION: HUMAN TRANSFERASE PROTEINS
FILE REFERENCE: PF-0592 PCT
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CURRENT FILING DATE: 2002-03-12
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                                                                                                                                                                                                                                                                                                                                                                                                         1 MLLPK--KMKLLLPLVSQMAILALPFHMYSHNISSLSMKAQPERMHVLVLSSWRSGSSFV
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                                                                                                      EADPRLRVVNEVCRSHVRIAEAALHKPPPPLQDRYRLVRYEDLARDPLTVIRELYAPTGL 293
                                                                                                                                                                                                                                         ROSSLFOWENSRALCSAPACDIIPODE-SSPGLTAGSCAVNSPLKLLEKACRSYSHVVLK 177
                           GLTPQLQTWIHNITHGSGPGARREAFKTTSRDALSVSQAWRHTLPFAKIRRVQELCGGAL 353
                                                                                                                                                                                               EVRFFNLQVLYFILSDPALNIRIVHLYRDPRAVLRSREQTAKALARDNGIVLGTNGTWV- 233
EFLPHLQTWVHNITRGKGMG--DHAFHTNARDALNVSQAWRWSLPYEKVSRLQKACGDAM
                                                                            EVRFFNLOSLYPLLKDESLNIHIVHLVRDERAVFRSRERTKGDLMIDSRIVMGQHEQKLK 237
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    CORLEY, Neil C.
GUEGLER, Karl J.
BAUGHN, Mariah R.
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354

QLLGYRSVHSELEQRDLSLDLL 375

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APPLICANT: MITAMATEN, TAKASHI
TITLE OF INVENTION: POLYPEPTIDE OF M-ACETYLG
TITLE OF INVENTION: DNA ENCODING THE SAME
FILE REFERENCE: TOYAM41.001AUS
CURRENT APPLICATION NUMBER: US/09/263,023
CURRENT FILING DATE: 1999-03-05
EARLIER APPLICATION NUMBER: JP 10/54007
EARLIER FILING DATE: 1998-03-05
EARLIER APPLICATION NUMBER: JP 10/17844
EARLIER APPLICATION NUMBER: JP 10/17844
ENCLIER FILING DATE: 1998-06-24
NUMBER OF SEQ ID NOS: 10
SOFTWARE: FASTSEQ for Windows Version 3.0
SEQ ID NO 4
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                                                                                           RESULT 8
US-09-471-867-4
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; TYPE: PRT
; ORGANISM: Homo sapiens
US-09-263-023-4
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Best Local Similarity
                                                       Sequence 4, Application US/09471867 Patent No. 6455289
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               APPLICANT: Muramatsu, Hidek
APPLICANT: Kadomatsu, Kenji
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NPPLICANT: Muramatsu, Hideki
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PPLICANT: Habuchi, Osami
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CANT: Muramatsu,
               INFORMATION:
ANT: Uchimura, Kenji
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    Application US/09263023
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Hideki
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Pred. No. 4e-63;
6; Mismatches 117;
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US-09-471-867-4
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LENGTH: 484
Sequence 6471, Applicati
Patent No. 6812339
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TITLE OF INVENTION: POLYPEPTIOE OF N-ACETYLGLUCOSAMINE-6-0-SULFOTRANSFERASE
TITLE OF INVENTION: DNA ENCODING THE SAME
FILE REFERENCE: TOYAN41.001AUS
CURRENT APPLICATION NUMBER: US/09/471,867
CURRENT APPLICATION NUMBER: US/09/471,867
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FILING DATE: 1999-03-05
APPLICATION NUMBER: UP 10-54007
FILING DATE: 1998-03-05
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FILING DATE: 1998-06-24
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Habuchi, Osami
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36.8%; Pred. No. 4e-
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TITLE OF INVENTION: POLYMORPHISMS IN KNOWN GENES ASSOCIATED TITLE OF INVENTION: WITH HUMAN DISEASE, METHODS OF DETECTIC FILE REFERENCE: CL001307
CURRENT APPLICATION NUMBER: US/09/949,016
CURRENT FILING DATE: J2000-04-14
PRIOR APPLICATION:

DETECTION AND USES THEREOF

PRIOR APPLICATION NUMBER: 60/241,755
PRIOR FILING DATE: 2000-10-20
PRIOR APPLICATION NUMBER: 60/237,768
PRIOR FILING DATE: 2000-10-03

APPLICATION NUMBER: 60/237,768
FILING DATE: 2000-10-03
APPLICATION NUMBER: 60/231,498
FILING DATE: 2000-09-08